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EXAMINER

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.



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**BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES**

Application Number: 10/606,745
Filing Date: June 27, 2003
Appellant(s): GLUCKMAN ET AL.

Erin M. Dunston
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed March 21, 2008 appealing from the Office action mailed July 20, 2007.

Appellants' Brief begins with a section "I. Brief Procedural History", not explicitly provided for in 37 CFR 41.37(c)(1). As a result, the section numbers in Appellants' Brief are one greater than the section numbers occurring in the rule. However, all items under the

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appropriate headings and in the order indicated in 37 CFR 41.37(c)(1) are present in the Brief.

The section numbers in the Answer are those specified in MPEP 1207.02.

(1) Real Party in Interest

A statement identifying by name the real party in interest is contained in the brief.

However, it should be noted that section 4 of the Office action mailed July 20, 2007 objects to this reissue application due to the failure of the assignee to establish ownership interest in the patent for which reissue is being requested, and points out several inconsistencies among the papers which Applicants/Appellants have filed in order to establish the consent of the assignee.

(2) Related Appeals and Interferences

The following are the related appeals, interferences, and judicial proceedings known to the examiner which may be related to, directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal:

See the Brief, section III. The only related appeal, interference, or judicial proceeding known to the examiner is Interference No. 104,553, a copy of whose Decision on Motions and Judgment are attached as Appendix 3 of the Brief.

(3) Status of Claims

The statement of the status of claims contained in the brief is correct.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is correct.

(6) Grounds of Rejection to be Reviewed on Appeal

The appellant's statement of the grounds of rejection to be reviewed on appeal is correct.

GROUND OF REJECTION NOT ON REVIEW

The following grounds of rejection have not been withdrawn by the examiner, but they are not under review on appeal because they have not been presented for review in the appellant's brief. As set forth in section 6 of the Office action mailed July 20, 2007, all claims are rejected under 35 U.S.C. 251 because of a need for a supplemental reissue oath/declaration under 37 CFR 1.175(b)(1). As set forth in the rejection, and as discussed in MPEP 1444(II), the supplemental reissue oath/declaration need not be, and preferably is not, submitted until the application is otherwise in condition for allowance.

(7) Claims Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct.

(8) Evidence Relied Upon

Interference No. 104,553, Decision On Motions, mailed March 25, 2003.

Interference No. 104,553, Judgment, undated.

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claims 16, 28, 66, 67, 72, and 73 are rejected under 35 U.S.C. 103 as being estopped on the merits by final judgment in Interference No. 104,553. In the section of the interference count which corresponds to claim 1 of U.S. Patent No. 5,714,460, damaged glia or other non-cholinergic cells are treated with IGF-1 or biologically active analogues thereof. The

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interference count does not recite that the CNS injury predominately affects glia. It would have been obvious to one of ordinary skill in the art at the time Applicants' invention was made to treat glial cells damaged by CNS injury which predominantly affects glia, because the interference count specifically recites that injured glia cells are to be treated, and the lack of injury to other types of cells would not have been expected to interfere with the ability of IGF-1 and its analogues to treat injured glia cells. With respect to claims 66, 67, 72, and 73, these claims recite the same or broader limitations as are recited in claims 8-9 of the '460 patent, which were designated as corresponding to the count. Gluckman filed a motion in the interference contesting the designation of this claim as corresponding to the count, which motion was denied (see pages 24-26 of the Decision On Motions). Accordingly, claims 66, 67, 72, and 73 are deemed obvious over that section of the count which corresponds to claim 1 of U.S. Patent No. 5,714,460. See 37 CFR 41.127(a) and MPEP 2308.03, Examples 2 and 3 (Rev. 4, October 2005). In the paper titled "Notice Under 37 C.F.R. §1.178(b)" filed June 27, 2003, Applicants refer to footnote 17 of the Decision On Motions in the interference as indicating that Applicants would not be estopped from pursuing in a reissue application narrower claims that would not have been obvious in view of the lost count. However, the basis for this approach is that the reissue claims must be nonobvious over the lost count. As indicated above, the current reissue claims remain obvious over the lost count.

Claims 16, 28, 66, 67, 72, and 73 are rejected under 35 U.S.C. 102(g) and/or 103 as being estopped on the merits by final judgment in Interference No. 104,553. In the section of the interference count which corresponds to claim 1 of U.S. Patent No. 5,714,460, damaged glia or other non-cholinergic cells are treated with IGF-1 or biologically active analogues thereof. With

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respect to claims 16, 28, 66, 67, 72, and 73, these claims recite the same or broader limitations as is recited in claims 8-9 of the '460 patent, which were designated as corresponding to the count. Gluckman filed a motion in the interference contesting the designation of this claim as corresponding to the count, which motion was denied (see pages 24-26 of the Decision On Motions). Further, Applicants' specification at column 1, lines 44-46, acknowledges that multiple sclerosis is a disease of the CNS which causes the loss of oligodendrocytes (which are a type of glia cells). This section of Applicants' specification is quoted in section [19] of the Decision On Motions. See also section [93] of the Decision On Motions. Accordingly, the count, which suggests treating glial cells which are injured by multiple sclerosis, also suggests the broader limitation of treating glial cells damaged by CNS injury which predominantly affects glia. Claims 16, 28, 66, 67, 72, and 73 are deemed obvious over that section of the count which corresponds to claim 1 of U.S. Patent No. 5,714,460. See 37 CFR 41.127(a) and MPEP 2308.03, Examples 2 and 3 (Rev. 4, October 2005). In the paper titled "Notice Under 37 C.F.R. §1.178(b)" filed June 27, 2003, Applicants refer to footnote 17 of the Decision On Motions in the interference as indicating that Applicants would not be estopped from pursuing in a reissue application narrower claims that would not have been obvious in view of the lost count. However, the basis for this approach is that the reissue claims must be nonobvious over the lost count. As indicated above, the current reissue claims remain obvious over (or even anticipated by) the lost count.

(10) Response to Argument

Certain of Appellants' claims are rejected on the basis of interference estoppel. The basis of the first rejection is that, because the interference count recites treating glia cells damaged

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from CNS injury, the interference count suggests treating glia cells damaged from CNS injury in which the predominant effect is to glia cells. The interference count suggests treating injured glia cells even when there is a relative lack of injury to other types of cells. The basis of the second rejection is that during the interference, claims drawn to the treatment of glial cells injured by multiple sclerosis were designated as corresponding to the count. Therefore, those of the current claims which recite or embrace treatment of glial cells injured by multiple sclerosis should also be considered to correspond to the count and are at least suggested thereby. The new claim limitation that the CNS injury predominantly affects glia cells does not provide an additional basis for distinguishing claims drawn to the treatment of glial cells injured by multiple sclerosis, because the new claim limitation is merely a known and defining characteristic of multiple sclerosis.

Appellants' essential contention is that that they should not be estopped from adding non-interfering claims to this reissue application. See, e.g., page 10, lines 1-2, of the Brief; and the paragraph bridging pages 11 and 12. However, this contention begs the question as to whether or not the claims at issue are non-interfering claims, i.e. whether the claims at issue are novel and unobvious over the interference count. See also the Decision On Motions, page 23, footnote 17: "[Gluckman] would not be estopped (37 C.F.R. §1.658(C)) from filing a reissue application seeking narrower claims that would not have been obvious in view of the subject matter of the lost count to the extent Gluckman's specification supports such claims." For the reasons set forth in the two rejections, the examiner's position is that claims 16, 28, 66, 67, 72, and 73 are not non-interfering claims, and therefore Appellants can be estopped from their allowance in this reissue application.

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At page 9, first full paragraph, through page 10, line 8, of the Brief, Appellants discuss the Board's interpretation of the Interference count, and point out that the Board found that Gluckman's claimed method (forming part of the Interference count) could unintentionally also treat cholinergic cells. In response to this, in reissue claims 16, 28, 66, 67, 72, and 73, Appellants have added the limitation "wherein said CNS injury predominantly affects glia". However, it should be noted that the added limitation addresses the types of injuries embraced by the claim, and does not (at least not directly) address whether non-glial cells can be treated by the claimed method. It is the types of cells which can be treated, rather than the type of CNS injury, which was the subject of the cited paragraph from the Decision On Motions. In any event, the term "predominantly" does not mean that glia exclusively are injured; the term permits other types of CNS cells to be injured, even in significant amounts. Appellants do not currently claim a method of targeted treatment of one type of CNS cells to the exclusion of other CNS cells. The claim limitation added in this reissue application does not counteract or nullify the interpretation the Board made of the Interference count. Further with respect to ¶ 26 of the Decision On Motions discussed in the Brief, the cited paragraph states: "neither party discloses a targeted treatment in a patient of one type of CNS cell to the exclusion of other CNS cells. Gluckman specifically teaches that IGF-1 is 'a potent non-selective trophic agent for several types of neurons in the CNS' " (emphasis added). If Gluckman does not disclose targeted treatment in the patent involved in interference, Gluckman will not be able to claim targeted treatment in this reissue application without the introduction of new matter. The distinction which the Brief finds between the rejected claims and the Interference Count is not supported by claim language found in the rejected claims.

In several sections of the Brief (see, e.g., page 10, first full paragraph, through page 11, first full paragraph; page 12, second full paragraph; etc.), Appellants contend that the examiner has not satisfied the four-step *Graham* analysis required of an obviousness rejection. However, the rejection under 35 U.S.C. 103 discusses the content of the Interference count, discusses the difference between the claimed invention and the Interference count, and resolves the differences between the claimed invention and the Interference count. With respect to establishing the level of ordinary skill in the art, specifying a particular level of skill is not necessary where the prior art itself, i.e. the Interference count, reflects an appropriate level. See MPEP 2141.03(II). Appellants do not substantively traverse the examiner's resolution of the differences between the claimed invention and the Interference count.

With respect to instant claims 66 and 67, claims 8 and 9 of the Gluckman et al patent, U.S. Patent No. 5,714,460), were designated by the Decision On Motions as corresponding to the count. See page 26, last paragraph. Claims 8 and 9 of Gluckman 460 recite a method wherein the CNS injury is multiple sclerosis or a demyelinating disorder. Instant claims 66 and 67 also recite a method wherein the CNS injury is multiple sclerosis or a demyelinating disorder. Assuming that instant independent claim 16 does not patentably distinguish over the Interference count, then instant dependent claims 66 and 67 will not further patentably distinguish over independent claim 16, just as dependent claims 8 and 9 of Gluckman 460 were found to correspond to the Interference count.

With respect to instant claims 28, 72, and 73, the arguments in the Brief (see pages 13 - 16) parallel those set forth with respect to claims 16, 66, and 67. Note also that the portions of

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the Interference count corresponding to Gluckman 460 claim 1 and Gluckman 373 claim 1 recite biologically active analogues of IGF-1.

With respect to the rejection under 35 U.S.C. 102(g) and/or 103, the basis of this rejection is that claim 8 of Gluckman 460, drawn to the treatment of glial cells injured by multiple sclerosis, was designated as corresponding to the count. All of rejected reissue claims 16, 28, 66, 67, 72, and 73 either recite or embrace treatment of glial cells injured by multiple sclerosis. Whether the claimed injury is characterized using the descriptive terminology “CNS injury predominantly affects glia” and/or “demyelinating disorder”, the rejected claims still recite or embrace treatment of glial cells injured by multiple sclerosis. The choice of descriptive terminology does not alter that fact that Appellants continue to claim a method of treating multiple sclerosis by administering IGF-1 or analogs thereof. Because claims drawn to the same method were designated as corresponding to the Interference count, to which count Appellants were not awarded priority, Appellants are not subsequently entitled to claim the same method in this reissue application, no matter what terminology is chosen to describe the method. The statement in the Brief at page 21, second full paragraph, that “Claim 67’s additional limitation, that CNS injury is multiple sclerosis, is absent from the ‘553 Interference”, is not in accord with, e.g., pages 25-26 of the Decision On Motions.

At pages 25-26 of the Brief, Appellants contend that “a party cannot seek to add a claim to an application in interference and request that it be designated as not corresponding to the Count”; that “Gluckman would not be estopped from filing a reissue application seeking narrower claims that would not have been obvious in view of the subject matter of the lost count”; that “estoppel does not attach because Appellants were not able to add such a claim

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during the course of the ‘553 Interference’; etc. However, none of these arguments are applicable to the instant fact situation. Claims drawn to the treatment of multiple sclerosis were present in the application in interference and were designated as corresponding to the count. Instant claims 16, 28, 66, 67, 72, and 73 are drawn to the same method of treating multiple sclerosis, or to a method which generically encompasses a method of treating multiple sclerosis. Estoppel does attach to claims which re-present the same subject matter as, or more broadly claimed subject matter than, the subject matter claimed in the applications involved in the Interference.

At pages 20-31 of the Brief, Appellants re-present the same arguments made earlier with respect to the rejection under 35 U.S.C. 103, e.g., the issue of targeted treatment and the new claim limitation "CNS injury predominantly affects glia"; the issue of whether the *Graham* procedure for determining obviousness has been followed; etc. The examiner's earlier-presented response to these arguments continues to apply to the rejection under 35 U.S.C. 102(g) and/or 103.

(11) Related Proceeding(s) Appendix

Copies of the court or Board decision(s) identified in the Related Appeals and Interferences section of this examiner's answer are provided in Appendix 3 of Appellant's Brief.

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For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

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